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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/104,529 08/12/93 CLASSEN

18N2/1120

BROWDY & NEIMARK
419 SEVENTH STREET, N.W.
WASHINGTON, DC 20004

J	CLASSEN1
EXAMINER	

VOGEL, N

ART UNIT	PAPER NUMBER
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16

1805

DATE MAILED:

11/20/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 2-14, 16-18, 21-35 and 37 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 2-14, 16-18, 21-35 and 37 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 O.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

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The finality of the previous Office action has been withdrawn.

Claims 2-14, 16-18, 21-35, and 37 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specification which discloses a method of immunizing mice using particular immunogens and schedules of vaccinations as set forth in Examples 1-3 of the specification See M.P.E.P. §§ 706.03(n) and 706.03(z).

The claims as drafted are drawn to methods of immunizing any mammal, wherein said immunization results in a decrease in the incidence of diabetes mellitus, using a wide variety of types of immunogens and schedules of immunization. However, it would require undue experimentation to practice the invention throughout its scope. The claims encompass virtually limitless numbers of possible combinations of immunogens and vaccination schedules, and furthermore, are directed to methods of immunizing any mammal. The experimentation that would be required to determine which of these virtually limitless numbers of embodiments have the desired effect, i.e. the reduction in the occurrence of diabetes mellitus, would be undue. There is no guidance in the specification regarding types of immunogens, amounts of immunogens, specific times of immunization, which would be effective for hosts as diverse as those encompassed by the claims. It cannot be predicted which types of immunogens, in

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what amounts, at what specific times, and by what particular route, of all of those encompassed by the claims, would result in the desired effect. The epidemiological data presented regarding the incidence of diabetes mellitus and vaccination schedules for humans do not provide any guidance as to which immunogens, at what specific times, in what amounts, and by what route of immunization, would be effective in reducing the incidence of diabetes mellitus. It is not predictable that the animal data disclosed in Examples 1-3, would be directly extendable to other mammals. Each mammal has a particular rate of development, particular responses to immunogens, and susceptibilities to disease, and times and types of immunization would be predicted to have widely varying affects on any particular mammal. Although applicants have set forth a plethora of combinations of vaccination schedules that may be tried for any particular mammal, this does not constitute an enabling disclosure, since undue experimentation would be required to practice the invention, due to the lack of guidance and the scope of the claims. The patent application should not constitute an invitation to experimentation.

Claims 2, 7, 11-14 and 16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "said immune-mediated disorder". However, claim 3 on which claim 2 depends does not contain the phrase "immune-mediated disorder".

Claim 7 recites "said at least one immunogen other than BCG". However, claim 3 on which claim 7 depends does not recite this phrase.

Claim 9 is dependent on cancelled claim 1.

Claims 11-14 recite "the disorder". However, claim 3 on which these claims depend do not recite the word "disorder", and it is not clear to what these claims are referring by this word.

Claim 16 recites "said chronic immune mediate disorder". However, claim 3 on which it depends does not recite this term.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-0278. The examiner can normally be reached on Monday through Friday from 7:30AM to 3:30PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mindy Fleisher, can be reached on (703)308-0407. Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. Papers should be faxed to Art Unit 1805 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1805 FAX number is (703) 308-0294. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. T. Vogel
**NANCY T. VOGEL
PATENT EXAMINER
GROUP 1800**

NTV
October 31, 1995